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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,205	SUZUKI, SHIGEKI	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,10-16 and 18* is/are rejected.

7)☒ Claim(s) *6-9 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/1/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are pending. Claims 1 and 17 are withdrawn as being drawn to a non-elected invention. Claims 2-16 and 18-19 are under consideration in the instant office action.

Election/Restrictions

Applicant's election with traverse of Group II (claims 2-16 and 18-19) in the reply filed on April 19, 2007 is acknowledged. The traversal is on the ground(s) that Applicant noted that claim 17 is allegedly dependent from claims 1-16. This is not found persuasive because the alleged dependency is recited with regards to an intended use of a composition. A recited intended use of a composition typically does not materially affect the required components of a claim, as is the case in this instance. Thus, the intended use of the composition of claim 17 is not considered as rendering claim 17 dependent from claims 1-16.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The disclosure is objected to because of the following informalities: the word "chondroitin sulfate" is misspelled in paragraph [0044] as "condroitin sulfate".

Appropriate correction is required.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claims 19 is objected to because of the following informalities: there is disagreement between the article "an" and the plural word "acids" on line 7 of said claim. Appropriate correction is required.

Claims 6-9 and 19 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim ***cannot depend from any other multiple dependent claim.*** See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (1) providing hemostasis to a wound using carboxymethyl celluloses, carboxyethyl celluloses, oxycelluloses, agaroses, chitins, chitosans, hyaluronic acids, starches, glycogens, alginates, pectins, dextrans, chondroitin sulfates, gelatins, collagens and (2) prevention of organ adhesion using collagens, does not reasonably provide enablement for (1) hemostasis utilizing any biopolymer nor (2) the prevention of organ adhesion using any biopolymer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

An analysis based upon the Wands factors is set forth below.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993),. See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman (230 USPQ 546, 547 (Bd Pat App Int 1986)). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Breadth of Claims

Applicants' claims are broad because the claimed methods utilize any biopolymer to provide for (1) hemostasis and (2) the prevention of organ adhesion.

Nature of the invention/State of the Prior Art

A search of the art indicates that the prior art only recognizes that collagen (U.S. Patent No. 7,195,912) and ketotifen (U.S. Patent No. 5,891,460) as compounds capable of preventing organ adhesion. Only collagen is a biopolymer. The prior art does not acknowledge that the property of preventing organ adhesion is characteristic of all known and unknown biopolymers. For example, the prior art does not teach that biopolymers, such as insulin, DNA, RNA, or starch, as exhibiting the property of preventing organ adhesion. Regarding the property of

conferring hemostasis to a wound, the art recognizes biopolymers, such as collagen, calcium phosphates (e.g. hydroxyapatite), celluloses (JP 2003062057A; English Abstract Only), albumin (U.S. Patent No. 4,427,651), globulin (U.S. Patent No. 4,427,651), fibrinogen (U.S. Patent No. 4,427,651), hyaluronic acid (JP 2003062057A; English Abstract Only), chitin (JP 2003062057A; English Abstract Only), chitosan (JP 2003062057A; English Abstract Only), pectin (JP 2003062057A; English Abstract Only), chondroitin sulfate (JP 2003062057A; English Abstract Only), cellulose oxide (JP 2003062057A; English Abstract Only), and starch (JP 2003062057A; English Abstract Only) exhibit this property.

Level of One of Ordinary Skill & Predictability/Unpredictability in the Art

The level of a person of ordinary skill in the art is high, with ordinary artisans having advanced medical and/or scientific degrees (e.g. M.D., Ph.D., Pharm. D. or combinations thereof). There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427, F. 2d 833, 166, USPQ 18 (CCPA 1970).

Guidance/Working Examples

The instant specification provides no working examples regarding formulations comprising specific biopolymers. The specification states that suitable biopolymers for providing hemostasis, preventing organ adhesion, preventing keloids, healing wounds, closing wounds, and sealing wounds are carboxymethyl celluloses, carboxyethyl celluloses, oxycelluloses, agaroses, chitins, chitosans, hyaluronic acids, starches, glycogens, alginates, pectins, dextrans, chondroitin sulfates, gelatins, collagens. No data is provided in the specification supporting applicant's assertion that all the biopolymers listed in paragraph [0044]

exhibit the property of preventing organ adhesion. Thus, it would prevent an undue serious burden upon a person of ordinary skill in the art at the time of the instant invention to rigorously test every known biopolymer and determine which biopolymers exhibit the properties of affecting wound homeostasis and preventing organ adhesion.

In conclusion, the specification, while being enabling for (1) providing hemostasis to a wound using carboxymethyl celluloses, carboxyethyl celluloses, oxycelluloses, agaroses, chitins, chitosans, hyaluronic acids, starches, glycogens, alginates, pectins, dextrans, chondroitin sulfates, gelatins, collagens and (2) prevention of organ adhesion using collagens, does not reasonably provide enablement for (1) hemostasis utilizing any biopolymer nor (2) the prevention of organ adhesion using any biopolymer.

To emphasize this point the Examiner points Applicants to "Genentech, 108 F.3d at 1366 and *Brenner v. Manson,* 383 U.S. 519, 536, 148 USPQ 689, 696 (1966)" which states,

> "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 2-5, 11, 15-16, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-3 are indefinite because it is unclear to what the organ is being prevented from adhering.

Claim 2 is vague, because it is unclear what constitutes a "type of fine particle of a biopolymer" and what required features distinguish different types of fine particles of a biopolymer.

Claim 11 is indefinite because it is unclear what Applicant considers a "type of a component" as well as what defining characteristics distinguish the two "types of components."

Claim 11 is indefinite because it is unclear what is "the other vessel." Claim 11 refers to "containers" but does not specify the quantity of containers, thus it is unclear whether there are two containers, three, four, etc. and a person of ordinary skill in the art at the time of the instant invention would be unable to ascertain what container is "the other vessel."

Claim 11 recites the limitation "the vessel" in lines 7-8. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "the first half of the spraying" in lines 9-10. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "the gas input portion side" in lines 12-13. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 is indefinite because it is unclear from the claim language whether the phrase," the first half of the spraying," is intended to refer to a chronological period of time in the spraying or to something else. Appropriate correction and clarification is required.

Claim 11 is vague, because it is unclear whether each of the unspecified number of containers contain two types of respectively different components or whether each container contains a single different type of component.

Claim 11 is indefinite, because it is unclear what would constitute, "gradually varying the concentration of the respectively sprayed components," especially what rate of change in the concentration of the components would be considered a gradual variation. Thus, a person of ordinary skill in the art would be unable to ascertain the metes and bounds of the phrase "gradually varying the concentration of the respectively sprayed components."

Claim 12 is vague; because it is unclear whether a single biopolymer or both "types of biopolymer" are included in the set of fine powder and solution and whether the "set of solutions" is referring to two solutions comprising only one of each of the two "types of biopolymers" or whether the solutions recited comprise both "types of biopolymer."

Claim 15 is indefinite because it is unclear what is the "other coagulation factor" recited in lines 4-5 of said claim.

Claim 15 is confusing regarding which solutions and/or components are contained or passed through which capillary tube (i.e. one capillary tube vs. the other capillary tube), as well as whether it is required for the solutions and/or other components recited in said claim to pass through each of the two capillary tubes or if passage through one of the capillary tubes is sufficient to meet the limitations of claim 15. It is also unclear whether the two solutions are required to mix within the micro tube or whether mixing occurs solely after spraying from the tip of the micro tube. Appropriate correction and clarification is required.

Claim 16 is vague because it is unclear what quantity of fibrinogen is required for fibrinogen to be considered the "chief constituent". The instant specification does not define the term "chief constituent." Thus, a person of ordinary skill in the art would be unable to ascertain the metes and bounds of the term "chief constituent."

Claim 16 is vague because it is unclear what quantity of fibrinogen is required for fibrinogen to be considered the "main constituent". The instant specification does not define the term "main constituent." Thus, a person of ordinary skill in the art would be unable to ascertain the metes and bounds of the term "main constituent."

The remaining claims are rejected as depending from a rejected claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferdman et al. (U.S. Patent No. 5,951,531).

Applicant Claims

Applicant claims a method of administering a biopolymer comprising (a) fluidizing one or more types of fine particles of a polymer with a gas to prepare a homogenous mixed-phase fluid, (b) transferring the mixed-phase fluid through a micro-tube by flowing the gas, (c) spraying the fine particles of the biopolymer toward a target site from a tip (e.g. nozzle) providing a seal thereto, preventing adhesion to an organ, and healing a wound.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Ferdman teaches an apparatus and method for applying a particulate hemostatic agent (e.g. **collagen in the form of a powder**) to living tissue by **turbulently mixing said hemostatic agent from a finely dispersed fluid stream with a continuous gas stream** and spraying the dispersed hemostatic agent via an outlet conduit (i.e. tube) onto proximate living tissue (abstract; Figures 1, 2, and 3; col. 2, lines 37-50; col. 3, lines 6-25, 53-65; col. 4, lines 25-57; claims 1-9, 11, and 14-16). Other suitable hemostatic agents taught by Ferdman include cellulose and dried gelatin. Turbulent mixing of the gas stream and the finely dispersed hemostatic agent would inherently produce some vibration and thus reads on claim 4. Ferdman is silent as to the adjustment of the quantity of powder sprayed from the invented device by varying the powder concentration. The various conduits in Ferdman's invented apparatus read on micro-tubes. It is noted that what constitutes a "micro-tube" is not defined or described in Applicant's specification.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Ferdman does not anticipate the rejected claims, because Ferdman does not teach a micro-tube, per se and is silent regarding modifying the powder concentration to change the amount of powder sprayed.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to a person of ordinary skill in the art that Ferdman's device obviates the instantly claimed method, because Ferdman teaches essentially the same method. Ferdman does not explicitly state that the invented apparatus comprises micro-tubes. The only mention of the dimension of conduits/tubes in Ferdman's disclosure is that the nozzle (20) has a length of about 20 centimeters and the conduit as well as the conduit outlet has a diameter of 1.25 cm. Applicant's specification does not assert any unexpected or surprising results attributed to the use of a micro-tube. It would have been prima facie obvious to modify the physical dimensions of various tubes/conduits used in Ferdman's device to make the device less cumbersome, lighter, and easier to handle, such as by utilizing conduits (i.e. tubes) considered to be "micro-tubes." Turbulent mixing of the gas stream and the finely dispersed hemostatic agent would inherently produce some vibration and thus reads on claim 4. It would also have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention that increasing the concentration of a suspended or dissolved powder would increase the amount of powder sprayed from an apparatus in a given period of time and at a given flow rate, because concentration is a description of the amount of something in a given volume. Increasing the amount of a hemostatic agent in a fixed volume would obviously increase the amount of said agent deposited upon spraying the same fixed volume. The property of providing hemostasis is the defining characteristic of a hemostatic agent. Collagen is recognized as exhibiting the property of preventing organ adhesion. The property of sealing and healing a wound is inherent to sprayed collagen, as evidenced by Applicant's identification of collagens as biopolymers exhibiting these properties. For the aforementioned reasons, an ordinary skilled artisan would have had a reasonable expectation of success upon using

Ferdman's disclosed apparatus and method in a method of providing hemostasis, preventing organ adhesion, providing a seal, and healing a wound. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 10-14, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferdman et al. (U.S. Patent No. 5,951,531) as applied to claims 2-5 above, and further in view of Stilwell et al. (U.S. Patent No. 5,484,913) or Stroetmann (U.S. Patent No. 4,427,651).

Applicant Claims

Applicant claims (1) a method of administering a drug comprising (a) fluidizing one or more biopolymer fine particles, (b) fluidizing a finely powdered drug in different vessels, wherein (a) and (b) are affected by a gas flow, (c) spraying the drug powder first, (d) spraying the fine particles of the biopolymer to coat the drug component layer on the target site, thereby preventing diffusion and leakage of the drug to a location other than the target site; and (2) a method of administering a drug, comprising (a) connecting containers containing two types of different components in series with a micro-tube and spray the drug from a tip of the micro-tube onto a target site wherein one component is sprayed in a larger amount than the second component.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Ferdman were set forth above in the instant office action. Stilwell teaches **calcium-modified oxidized cellulose** hemostat and bioabsorbable fabrics containing said hemostat, which provided hemostasis faster than does either unmodified or sodium- or potassium-modified oxidized cellulose, wherein suitable medicaments for use with the cellulose hemostat **include thrombin, fibrinogen, and antifibrinolytics, preferably thrombin** (title; abstract, col. 4, lines 27-35; claims 1, 2, 4, 6, and 16-17). Stilwell states that it is well known that calcium plays an important role in hemostasis in the conversion of protothrombin to thrombin (col. 2, lines 28-42). The calcium modified oxidized cellulose reads on a cationic biopolymer. Both thrombin and fibrinogen are proteins and thus, these read on biopolymers.

Stroetmann teaches an enriched plasma derivative for enhancement of wound closure and coverage, including a sprayable preparation for accelerated hemostasis and optimized biochemical control of wound closure containing a powdery mixture of **thrombin** (16-60% w/w), 5-80% w/w of a desiccating and stabilizing agent (viz. **albumin, globulin, and/or fibrinogen**), and 1-10% w/w of a fibrinolysis inhibitor (title; abstract; col. 1, lines 60-67; col. 2, lines 19-33; col. 3, lines 45-60; col. 4, lines 3-7, 30-36, and 63-65; col. 7; lines 1-4 and 34-37; col. 8, lines 3-10; Examples I-VIII (see Table under col. 8); claims 1-8, 10, and 16-20). Stroetmann's compositions may also comprise **additional coagulation factors, such as factors XIII and IX**.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Ferdman lacks the express teaching of (a) connecting two or more containers containing different biopolymer compositions in series via a micro-tube, (b) a method wherein a drug is sprayed onto a target sited followed by a biopolymer solution onto said sprayed drug to prevent the drug's diffusion to sites other than the target site, (c) and a method wherein the two types of biopolymers is a combination of an anionic biopolymer a cationic biopolymer.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to a person of ordinary skill in the art to combine the teachings of Ferdman and Stilwell, because it is well known that calcium plays an important role in hemostasis. An ordinary skilled artisan would have been motivated to spray a wound with a known hemostasis agent, such as thrombin or fibrinogen to stop bleeding and to subsequently cover the sprayed drug (i.e. thrombin or fibrinogen) with Stilwell's calcium modified cellulose to enhance hemostasis. Stilwell does not state that the calcium-modified cellulose has sealing properties; however, the ability to provide a seal is an inherent property of the oxidized cellulose utilized by Stilwell, as evidenced by Applicants' disclosure that oxycelluloses exhibits this property. Oxycellulose is oxidized cellulose. A person of ordinary skill in the art at the time of the instant invention would have had a reasonable expectation of success upon combination of the prior art teachings, because Stilwell's compositions provide calcium and enhance hemostasis. Alternatively, a person of ordinary skill in the art at the time of the instant invention would also have been motivated to combine the teachings of Ferdman and Stroetmann, because Stroetmann's compositions provide accelerated hemostasis and optimized biochemical control of wound closure. A person of ordinary skill in the art would have had a

reasonable expectation of success upon combination of the teachings of Ferdman and Stroetmann because Stroetmann's compositions provide enhanced hemostasis and optimized would closure. Regarding the connection of two different containers in series to spray two different biopolymers this would have been prima facie obvious. This is especially obvious, wherein one of the containers contains thrombin, because thrombin is a sensitive enzyme and generally does not exhibit a long shelf life (Stroetmann: col. 4, lines 30-35). Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ferdman et al. (U.S. Patent No. 5,951,531) and Stilwell et al. (U.S. Patent No. 5,484,913) or Stroetmann (U.S. Patent No. 4,427,651) as applied to claims 10-14 and 16 above, and further in view of Kato (U.S. Patent No. 6,556,652).

Applicant Claims

Applicant claims a method of administering a drug characterized in that two capillary tubes are coaxially provided within a micro-tube, wherein one capillary provides the spray outlet for a fibrinogen composition and the other capillary provides an outlet for a second composition comprising thrombin or another coagulation factor.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Ferdman, Stilwell, and Stroetmann have been set forth above in the instant office action. Kato teaches a mass spectrometry apparatus and teaches that said apparatus may have **a nebulizer provided with plural coaxial capillary tubes** of different diameters (title, abstract, col. 5, lines 25-27).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Ferdman lacks the express teaching of a device wherein two capillaries are coaxially provided within a micro-tube. Kato is provided to demonstrate that the placement of two or more capillaries coaxially within a tube in a sprayer is a known configuration.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the instant invention that one could use a configuration of coaxial capillary tubes placed within a larger diameter tube to spray a plurality solution or suspension formulations. Coaxial capillary tubes within a larger bore tube are a known configuration for a nebulizer (i.e. sprayer). It would have been common sense to a person of ordinary skill in the art that one could include coaxial capillaries within a tube to prevent the mixing of the components transported via each respective coaxial tube until the time of spray. It would also have been prima facie obvious to a person of ordinary skill in the art that using two or more coaxial capillaries connected to different containers having different compositions therein, one could adjust the order of spraying of the different components to obtain optimal results. Thus, an ordinary skilled artisan would have had

a reasonable expectation of success upon using coaxial capillaries as a suitable configuration of the components of a sprayer used to spray two or more different compositions. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Other Matter

The Examiner respectfully requests that Applicants use proper Markush group language in claim 14: "a [the generic name of the required species] selected from ***the*** group consisting of [lists members of group]."

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references were deemed relevant because these teach various hemostasis compositions and methods: Soe et al. (U. S. Patent No. 6,403,570); Ezrin et al. (U.S. Patent No. 6,706,892); Martin (U.S. Patent No. 5,652,274), and Platz et al. (U.S. Patent No. 6,797,258).

Claims 2-5, 10-16, and 18 are rejected. Claims 6-9 and 19 were objected to and not further considered on the merits in the instant application due to these claims' improper multiple dependency. The specification is objected for the reasons stated in the instant office action. No claims under consideration in this office action are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo
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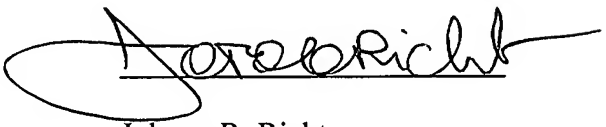

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